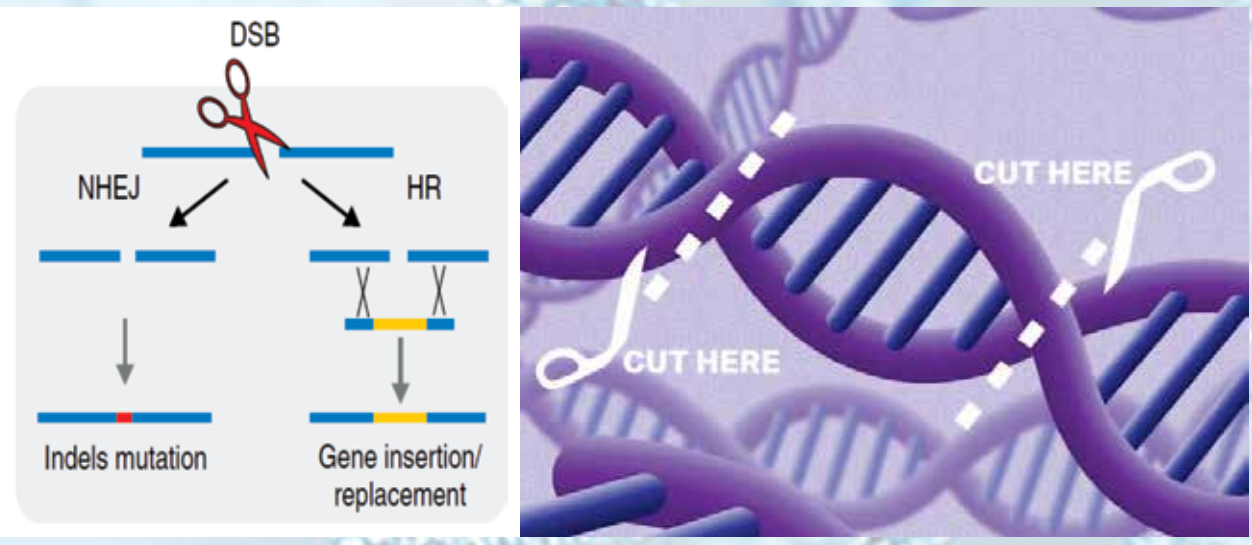
Harnessing Genome Editing for Crop Improvement – An Urgency

Policy Brief



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Preamble

Looking into our needs to achieve two important Sustainable Development Goals viz., zero hunger, and good health and well- being by 2030, the challenge to produce enough and adequately nutritious food is going to be a formidable task. By 2030, when India's population will be 1.51 billion from current 1.39 billion, the country would need around 345 million tonnes (mt) of food grains against the current production of 303 mt - almost 50 mt more i.e., additional 5 mt per annum. This has to be achieved against the current trend of declining natural resources - land, water, air and agrobiodiversity. In addition, there is an adverse impact of climate change on global food security, with rising temperature and increasing frequency of floods and drought.

In mid-sixties, major breakthrough in agricultural production was achieved mainly through breeding of dwarf high yielding varieties of wheat and rice, coupled with good agronomic practices including effective plant protection management. Now it is imperative that India continues to remain self-sufficient and emerge as a major food grain producer in the world. While classical plant breeding ushered in the Green Revolution, and molecular breeding brought further incremental as well as transformational genetic gains in the past 20 years, there is an urgent need to adopt more innovative tools for providing solutions to the new and emerging challenges, particularly climate change and nutritional security. In order to ensure this, science-led disruptive innovations like genome editing have to be scaled faster through enhanced investments, R&D capacities and enabling policy environment.

Fortunately, genome editing has emerged as a potent tool for precise, targeted and accelerated genetic

improvement of crop plants, which is particularly encouraging in view of the global slowing down of traditional plant breeding. The newly developed unique CRISPR/Cas9 technology, for which Dr. Emmanuelle Charpentier of France and Dr. Jennifer Doudna of USA received the 2020 Nobel Prize in Chemistry, is now being used extensively to modify DNA to breed varieties that can give sustainable yields across a wide range of environments and use less resources particularly water, nutrients and agro-chemicals. Successful outcomes of genome editing technology are citrus resistant to greening disease; banana resistant to panama disease; climate-resilient wheat and rice that can grow well under high temperatures as well as submergence and saline soils; tomatoes and ground cherries suited for efficient farming systems indoors and in the field; cassava, rice, wheat, millets, mustard with improved nutrition or low anti-nutritional traits; high oleic low linolenic (HOLL) soybean; non-browning mushroom; blight resistant rice, and gamma-amino butyric acid (GABA) tomato. These have been approved for production in USA, Japan and Colombia. These countries have kept genome edited crops that do not possess foreign DNA out of regulatory process thus enabling their quick release and commercialisation. Hence, adoption of this science- based technology is critical to reap the desired benefits in the larger national interest.

Recognizing its potential in accelerating crop breeding, both the Indian Council of Agricultural Research (ICAR) and the Department of Biotechnology (DBT) have initiated programs to harness the desired benefits at national scale. However, a coordinated approach coupled with enabling regulatory framework is still required to reap the benefits to the desired extent. In this context, the DBT with inputs from the National Academy of Agricultural Sciences (NAAS) has framed necessary guidelines based on scientific consultation involving senior experts. The draft guidelines have been further reviewed by an expert committee constituted by DBT and subsequently endorsed by the Regulatory Committee on Genetic Manipulation (RCGM). Same are now being reviewed for recommendation by the Genetic Engineering Appraisal Committee (GEAC) to the Ministry of Environment, Forest and Climate Change (MoEF&CC) for final approval by the Government. Obviously, to take advantage of this new innovation, there is an urgency for speedy decision in

the national interest. Several countries around the world have already framed clear guidelines for different categories of gene editing in plants, viz., SDN1, SDN2 and SDN3. Also, we shall need to consider the intellectual property rights protecting commercial use of genome editing technologies, for which negotiations with innovators are needed to seek a nationwide license for technology access and to have the end products released as national good for the benefit of all.

Along with, public awareness, identification of 'Centres of Excellence' for genetic improvement of different crops through genome editing is fully justified and needs immediate attention.

The Stakeholders Dialogue

In order to identify the required policy actions that would facilitate harnessing of genome editing for crop improvement, a "Stakeholders' Dialogue on Enabling Policies for Harnessing the Potential of Genome Editing in Crop Improvement" was held on 17 March 2021. The Dialogue was organized jointly by the Trust for Advancement in Agricultural Sciences (TAAS), a neutral 'Think Tank', in collaboration with Indian Council of Agricultural Research (ICAR), National Academy of Agricultural Sciences (NAAS), Biotech Consortium India Limited (BCIL), Tata Institute for Genetics and Society (TIGS), National Agri-Food Biotechnology Institute (NABI) and Biotechnology Industry Research Assistance Council (BIRAC). The objectives of the Dialogue were to: i) develop consensus on regulation of genome edited plants and catalyze approval of the regulatory policies, ii) deliberate on the mechanism of access to genome editing technologies for development and commercialization of genome edited crops by public and private sector enterprises, and iii) discuss policy directions for promoting application of genome editing technology for sustainable agriculture.

More than 70 participants representing a cross section of diverse stakeholders including Secretary, Department of Biotechnology (DBT); Secretary, Department of Agricultural Research and Education (DARE) & Director General, Indian Council of Agricultural Research (ICAR); Chairperson, Plant Variety Protection and Farmers' Rights Authority (PPV&FRA); Members of Genetic Engineering Appraisal Committee (GEAC); Chairman and Members of Review Committee of

Genetic Modification (RCGM); senior policymakers; regulators; senior scientists and the representatives of seed industry attended and participated in the deliberations.

Recommendations

During the dialogue, it was strongly felt that to harness the potential of genome editing for crop improvement and ensure food and nutritional security, being important sustainable development goals, there is an urgency to have in place an enabling policy environment. Hence, for the attention of policymakers, it was decided to bring out a Policy Brief highlighting the importance of action on the following recommendations:

1. Draft regulatory guidelines on genome editing as recommended by the Department of Biotechnology, using a consultative process involving National Academy of Agricultural Sciences (NAAS) and reviewed by RCGM, be cleared without delay by the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEF&CC). This will ensure quick Government approval for scaling the technology in the national interest. The participants of the dialogue were unanimous in recommending that products of genome editing that are shown to contain no foreign genetic material (SDN1) or whose altered genetic material is indistinguishable from natural gene pool, or is sourced from primary or secondary gene pool (SDN2), be exempted from biosafety testing as otherwise prescribed under the existing "Rules for the Manufacture, Use/ Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells (Rules,1989)". Hence, the genome edited plants exploiting available genetic variability within the same genus (cis) be simply treated as products of normal breeding method, including mutation, and be allowed for cultivation like normal varieties/ hybrids.

2. A mission-mode inter-institutional platform comprising centres of excellence on genome editing for specified crops be established on priority having mandate to: i) develop novel and more efficient genome editing tools, and have a national repository for newly

developed vectors and reagents, ii) develop genome edited crop varieties with desired traits for commercialization, and iii) build required human resource to effectively use genome editing.

3. Institute Biosafety Committee (IBSC) be strengthened and funded well to undertake its responsibilities more effectively. These be periodically monitored through an oversight role by the Review Committee on Genetic Modification (RCGM) under the Department of Biotechnology (DBT).

4. Strong public-private partnership is essential to reap the benefits of genome editing. It needs to be strengthened through incentives and enabling policy support by the government as also negotiated access to intellectual properties on genome editing and other technologies related to its use for development of crop varieties. Also, an effective coordination between the state and central government is needed to harmonise decisions relating to use of genome editing and commercialisation of end products.

5. Outreach and effective communication strategy for much-needed public perception is critical to reap the benefits of genome edited products. This would demand an aggressive public awareness campaign to ensure acceptance both by consumers and farmers. The role of NGOs/CSOs in creating the right perception needs to be appreciated and encouraged through desired incentives and rewards. In addition, a Status Paper on benefits of genome editing will help in creating needed awareness and ownership of this new technology.

6. Greater national effort to apply genome editing technology for targeted crop improvement by all concerned organisations/ institutions such as DBT, ICAR, CSIR, DST, DRDO and State Agricultural Universities (SAUs), through a national flagship program/platform is highly justified for which initial funding of Rs 1,000 crore be provided as a special grant. This could be a Mission Mode program with defined targets and outcomes in next 5 years monitored jointly by DBT and ICAR.

Progress Through Science

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